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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Simon Kroll

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EXAMINER

ARCHIE, NINA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,976	Applicant(s) KROLL ET AL.	
	Examiner Nina A. Archie	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41,44-49 and 61-73 is/are pending in the application.
- 4a) Of the above claim(s) 47,49,68 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41,44-46 and 64-67 is/are rejected.
- 7) ☒ Claim(s) 43,48,61-63,67,69,70,72 and 73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 3-3-08. Claims 41, 44-46, 49, and 68 have been amended. Claims 47, 49, and 68 have been withdrawn. Claims 1-40 and 42-43 have been cancelled. Claims 61-67 and 69-73 are new claims.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. The rejection of claim 48 under U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reason set forth in the previous office action.

Applicant arguments:

The rejection of claim 48 under 35 U.S.C. 112, second paragraph, is respectfully traversed. The metes and bounds of the phrase "under conditions of moderate to high stringency" is well understood by those of ordinary skill in the art, since the terms "moderate stringency" and "high stringency" are well defined terms in the art. For example, the specification, page 10, line 24 to page 11, line 3, provides examples of the conditions needed to achieve "moderate stringency" and "high stringency", and how to vary such conditions between "moderate stringency" and "high stringency". Furthermore, Ausubel et al., a well known reference work, also provides details of conditions which will achieve "moderate stringency" and "high stringency". Accordingly, claim 48 is not indefinite. Withdrawal of this ground of rejection is respectfully

requested.

Examiner's Response to Applicant's Arguments:

Examiner accepts Applicant's arguments but they are not persuasive. The recitation "moderate to high stringency" is not defined in the specification nor is the range known in the art. Therefore one skilled in the art would not be able to interpret the recitation "under conditions of moderate to high". Therefore the rejection is maintained.

As outlined previously, As to claim 48 a dependent claim recites the phrase "moderate to high". However, neither the claim nor the specification clearly defines nor sets forth the meaning or means to assess "moderate to high". "Moderate to high" has no art defined meaning with respect to an attenuated bacteria. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of "moderate to high" nor how to assess such. It is unclear how to interpret what is considered "moderate" and inasmuch as it is not a recognized term and not defined in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

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filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3a) The rejection of claims 41-42 and 44-46 under 35 U.S.C. 102(b) as being anticipate by Fuller et al 2000 Microbial Pathogenesis Vol. 29 pgs. 39-51 is maintained for the reasons set forth in the previous office action.

b) The rejection of claims 41-42 and 44-46 under 35 U.S.C. 102(b) as being anticipate by Segers et al US Patent No. 6,013,266 Date January 11, 2000 is maintained for the reasons set forth in the previous office action.

c) The rejection of claims 41-42 and 44-46 under 35 U.S.C. 102(e) as anticipated by Lowery et al US 6,790,950 Date September 14, 2004 (US Filing Date March 15, 2001) is maintained for the reasons set forth in the previous office action.

Applicant arguments:

The rejections of claims 41,42 and 44-46 under 35 U.S.C. 102, have been obviated by appropriate amendment. Claim 43 has been incorporated into claim 41. Withdrawal of these grounds of rejection is respectfully requested.

Examiner's Response to Applicant's Arguments:

Examiner accepts that the claims have been amended. However the claims are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium, having a mutation in a gene which comprises a nucleotide sequence selected from the group consisting of SEQ ID NOs.:1-56 and although the Applicant's have elected SEQ ID NO: 51. The claim recites a "mutation in a gene which comprises each SEQ ID NO: from SEQ ID NOs: 1-56. Examiner interpret the number of mutations that can be created to be an open ended number of mutation and any mutated gene can read on any mutated gene in SEQ NO: 51 which could be any sequnnce of the instant claim discussed above. Therefore Fuller et al teaches the instant claims as stated in the previous office action.

As outlined previously, the claims are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium, having a mutation in a gene which comprises a nucleotide sequence selected from the group consisting of SEQ ID NO.:1-56.

Fuller et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a single gene (see abstract, pg. 40 "Results Section", pg. 46 "Materials and Methods Section"). Fuller et al teach *Actinobacillus pleuropneumoniae* strain grown in Brain Heart Infusion media thus Fuller et al anticipate a composition comprising the bacterium of *Actinobacillus pleuropneumoniae* (see pg. 46 "Materials and Methods Section"), wherein the composition comprises bacteria having different mutations in the same virulence gene (see abstract, pg. 40 "Results Section", pg. 46 "Materials and Methods Section").

Segers et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a single gene (see abstract,

column 5 lines 55-65, see columns 11-14). Segers et al teach *Actinobacillus pleuropneumoniae* bacterium in a pharmaceutically acceptable carrier thus Seger et al anticipate a composition comprising the bacterium of *Actinobacillus pleuropneumoniae* (see column 8 lines 50-60 and column 5 lines 55-65, see columns 11-14), wherein the composition comprises bacteria having different mutations in the same virulence gene (see abstract, column 5 lines 55-65, column 8 lines 50-60, columns 11-14).

Lowery et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a different genes (see abstract, column 3 lines 60-67, columns 4-6, column 7 lines 51-64, column 32 example 10). Lowery et al teaches a composition, comprising the bacterium of an attenuated *Actinobacillus pleuropneumoniae* bacterium, comprising a plurality of different attenuated *A. pleuropneumoniae* bacteria having different mutations in the same virulence gene (see abstract, column 3 lines 60-67, columns 4-6, column 7 lines 51-64, column 32 example 10).

New Grounds of Rejection

4. Claims 41, 64-67 are rejected under 35 U.S.C. 102(b) as being anticipate by Fuller et al 2000 *Microbial Pathogenesis* Vol. 29 pgs. 39-51.

Claims 41, 64-67 are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium, having a mutation in a gene which comprises a nucleotide sequence selected from the group consisting of SEQ ID NO.:1-56.

Fuller et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a single gene (see abstract, pg. 40 "Results Section", pg. 46 "Materials and Methods Section"). Fuller et al teach *Actinobacillus pleuropneumoniae* strain grown in Brain Heart Infusion media thus Fuller et al anticipate a composition comprising the bacterium of *Actinobacillus*

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pleuropneumoniae (see pg. 46 "Materials and Methods Section"), wherein the composition comprises bacteria having different mutations in the same virulence gene (see abstract, pg. 40 "Results Section", pg. 46 "Materials and Methods Section").

Examiner interpret the number of mutations that can be created to be an open ended number of mutation and any mutated gene can read on any mutated gene in SEQ NO: 51 which could be any sequence of the instant claim discussed above. Therefore Fuller et al teach drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium, having a mutation in a gene which comprises a nucleotide sequence selected from the group consisting of SEQ ID NO.:1-56, wherein said gene comprises the nucleotide SEQ ID NO: 51, having a plurality of mutation occurring within the same gene. Furthermore, Fuller et al teach a composition, comprising the attenuated bacterium, comprising a plurality of different attenuated *A. pleuropneumoniae* bacteria, having different mutations in said gene.

5. Claims 41, 64-67 are rejected under 35 U.S.C. 102(b) as being anticipate by Segers et al US Patent No. 6,013,266 Date January 11, 2000.

Claims 41-42 and 44 are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium.

Segers et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a single gene (see abstract, column 5 lines 55-65, see columns 11-14). Segers et al teach *Actinobacillus pleuropneumoniae* bacterium in a pharmaceutically acceptable carrier thus Segers et al anticipate a composition comprising the bacterium of *Actinobacillus pleuropneumoniae* (see column 8 lines 50-60 and column 5 lines 55-65, see columns 11-14), wherein the composition comprises bacteria having different mutations in the same virulence gene (see abstract, column 5 lines 55-65, column 8 lines 50-60, columns 11-14). Examiner interpret the number of mutations that can be created to be an open ended number of mutation and any mutated gene can read on any mutated gene in SEQ NO: 51 which could be any sequence of the instant claim discussed above. Therefore Segers et al

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teach drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium, having a mutation in a gene which comprises a nucleotide sequence selected from the group consisting of SEQ ID NO.:1-56, wherein said gene comprises the nucleotide SEQ ID NO: 51, having a plurality of mutation occurring within the same gene. Furthermore, Segers et al teach a composition, comprising the attenuated bacterium, comprising a plurality of different attenuated *A. pleuropneumoniae* bacteria, having different mutations in said gene.

6. Claims 41, 64-67 are rejected under 35 U.S.C. 102(e) as anticipated by Lowery et al US 6,790,950 Date September 14, 2004 (US Filing Date March 15, 2001).

Claims 41 and 45-46 are drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium.

Lowery et al teaches an attenuated *Actinobacillus pleuropneumoniae* bacterium, wherein the bacterium has a mutation in a gene required for bacterial virulence, wherein the bacterium has a plurality of mutations, occurring within a different genes (see abstract, column 3 lines 60-67, columns 4-6, column 7 lines 51-64, column 32 example 10). Lowery et al teaches a composition, comprising the bacterium of an attenuated *Actinobacillus pleuropneumoniae* bacterium, comprising a plurality of different attenuated *A. pleuropneumoniae* bacteria having different mutations in the same virulence gene (see abstract, column 3 lines 60-67, columns 4-6, column 7 lines 51-64, column 32 example 10). Examiner interpret the number of mutations that can be created to be an open ended number of mutation and any mutated gene can read on any mutated gene in SEQ NO: 51 which could be any sequence of the instant claim discussed above. Therefore Lowery et al teach drawn to an attenuated *Actinobacillus pleuropneumoniae* bacterium, having a mutation in a gene which comprises a nucleotide sequence selected from the group consisting of SEQ ID NO.:1-56, wherein said gene comprises the nucleotide SEQ ID NO: 51, having a plurality of mutation occurring within the same gene. Furthermore, Lowery et al teach a composition, comprising the attenuated bacterium, comprising a plurality of different attenuated *A. pleuropneumoniae* bacteria, having different mutations in said gene.

Status of the Claims

7. No claims are allowed.

Claims 41, 44-46, 48, and 64-67 are rejected.

Claims 43 and 61-63, 69-70 and 72-73 are objected as being dependent on a base claim.

Claims 1-40, 42-43, and 50-60 are cancelled.

Claims 47, 49, 68, and 71 are withdrawn.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nina A Archie/

Examiner, Art Unit 1645

/N. A. A./

Examiner, Art Unit 1645

Nina A Archie

Examiner

GAU 1645

REM 3B31

/Mark Navarro/

Primary Examiner, Art Unit 1645